MARKET STUDY SERIES

A BRIEF FOR CANADIAN MANAGERS

AN OVERVIEW OF THE AUSTRALIAN HEALTH CARE INDUSTRY

CANADIAN TRADE COMMISSIONER SERVICE – AUSTRALIA
EXTERNAL AFFAIRS AND
INTERNATIONAL TRADE CANADA

AN OVERVIEW OF THE AUSTRALIAN

HEALTH CARE INDUSTRY

SUMMARY OF THE AUSTRALIAN HOME HEALTH CARE REPORT

The accompanying study of the current climate in the Australian Home Health Care industry is designed as an overview for Canadian manufacturers contemplating entering the Australian market.

Canada has not been a major player in either the Medical equipment or supplies fields which are dominated by the United States, Japan, West Germany, United Kingdom and local manufacturers.

However, as the Home Health Care industry is very much in its infancy in Australia, there would be opportunities for Canadian companies to enter the market on the ground floor, so to speak.

This report has been produced to provide information regarding the organization of the Australian Health Care System, the direction in which the industry appears to be heading and the possibilities for the emergence of an expanded Home Health Care System.

The study is realistic in that it points out weaknesses in the industry and some of the obstacles which need to be overcome.

If, having read the study, you require further information regarding the Australian market, please write, telex or fax the Canadian Consulate General, Sydney, detailing your company's contact information, advising which products you manufacture and would be interested in promoting.

Contact:

Mrs Eleanor Morton-Duff
Canadian Consulate General
8th Floor, 50 Bridge Street
SYDNEY NSW 2000
AUSTRALIA

Tel: (02) 231 7022
Tlx: AA 20600
Fax: (02) 223 4230

OVERVIEW OF THE AUSTRALIAN HEALTH CARE INDUSTRY

I. THE MARKET

A. Population

Australia is a country of some 7.7 million square kilometres - approximately four-fifths the size of Canada - occupied by a population approaching 17 million people.

Seventy-seven percent of its total population reside along the eastern seaboard, which encompasses the three major states of Victoria, New South Wales and Queensland. The population distribution across all states and territories is outlined in Table 1 below.

TABLE 1: AUSTRALIA: DISTRIBUTION OF POPULATION AS AT 30/12/1989

STATE	POPULATION	% OF TOTAL
New South Wales	5.761m	34.7
Victoria	4.315m	26.1
Queensland	2.838m	16.2
South Australia	1.423m	8.6
Western Australia	1.591m	9.0
Tasmania	0.451m	2.8
Northern Territory	0.156m	0.9
Australian Capital Territory	0.277m	1.7
TOTAL	16.800m	100.0

For reasons of historical, climatic and economic foundation, Australia's population is concentrated in state capital cities and other major cities in the south east quadrant. Some 85% of the total population live in these urban centres.

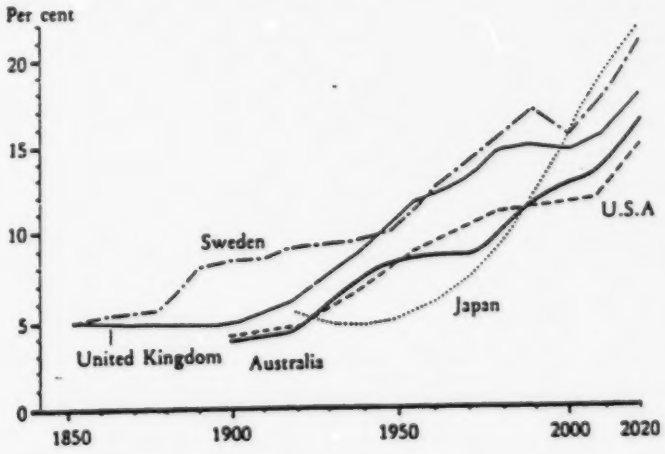
Outside these major areas of urban concentration, Australia's population is fairly sparsely distributed. Furthermore, the physical distance between these major centres is considerable. This factor is of particular relevance to anyone contemplating national product distribution as it has a marked impact on distribution costs and the ability to service the entire market.

B. Age Distribution

The combination of a decline in birth and mortality rates has resulted in a shift in the age composition of the population. As at June 1986, the median age was 31.0 years.

Australia is facing the greying of its population, as are many of the developed nations of the world. One current estimate shows that those over 65 years, despite being less than 10% population, accounted for 40% of all health care expenditures. With the growth of the aged, this imbalance will increase and projections which assume the same costs, expect that this section of the community will take at least half of the health budget in 2001.

Not only is the population ageing, but they are also living longer, which introduces new areas for concern ie. the increase of mental health problems such as Alzheimers disease, and the high incidence of migrant aged who do not have English as a first language.



Population aged 65 years and over as a percentage of the total population. *Sources:* Australian Bureau of Statistics (1985) *Projections of the populations of Australia, States and Territories 1984 to 2021* and various censuses and the Prime Minister's Secretariat, Japanese Government (1983).

II. THE ORGANIZATION OF HEALTH SERVICES

A. Health Insurance Commission

The primary responsibility for the provision of health care in Australia rests with the public sector, whose total expenditure in this area, at both the Commonwealth and State/Territory level, is almost double that of the private sector.

The Health Insurance Commission is a Commonwealth Statutory Authority. It was established in 1974 by the Health Insurance Commission Act 1973. Its function was to administer the Australian national health insurance program - known as Medibank - which was implemented on 1 July 1975. There have been many changes to health insurance arrangements since then and the organization now operates the private health insurance fund, Medibank Private, and administers the payment of benefits under the Government's Medicare program.

B. The Medicare Program

The increasing reliance on the public sector is largely attributable to the introduction of Medicare in February, 1984. Medicare is a system of universal health insurance and reflects the major health care objective of the present Labor Government, i.e. to ensure access to basic health services for all. The major feature of the Medicare system is the automatic entitlement to free or heavily subsidised medical and public hospital services. This program is administered by the Commission. A 1.25% levy is placed on income earners to fund the Medicare program. The program provides universal health cover on the basis of 85% of the Schedule fee for eligible medical and optometrical services and free shared ward accommodation, treatment by hospital doctors and out-patient services in public hospitals (with a flat 75% for hospital in-patient services from 1 August 1987). The medical cover provides for a maximum payment by the patient of $20 for any service and reimbursement of 100% of the Schedule fee once the total "gap" paid by the patient reaches $150 in any one financial year.

Private health insurance continues as a provider of supplementary benefits such as payment for private accommodation in public hospitals, payment for private hospitals accommodation and ancillary services and items not covered by Medicare such as dentistry, glasses and physiotherapy. The Australian government spends approximately A$20 billion per annum on health care or about 8% of the G.D.P.

C. Hospitals

In 1986, there were 1067 hospitals in Australia, of which 734, or 69%, are public (Government) hospitals. Of the 90,788 hospital beds available, some 77% are located in public hospitals.

As is evident from the above figures, public hospitals tend to be larger than their private counterparts. Additionally, the range of specialist services available tends to be broader, with many also operating as teaching hospitals. In general, Australia's public hospitals are thought to be amongst the world's finest, both in terms of facilties and expertise of their staff.

Responsibility for public hospitals is vested with each State and Territory, who have total control over the funding and expenditure of their hospitals. The Commonwealth Government's participation is limited to hospitals run by its Departments of Veterans' Affairs (10 hospitals) and Defence (3 small hospitals).

Federal and State government policies of cost containment, combined with the increasing cost of health care provision and the effects of major industrial disputes have placed enormous pressure on the public hospital system. Waiting lists for elective surgery have escalated to the point where delays of 12-18 months are commonplace, and existing physical and financial resources are simply inadequate to provide the standard of care, and in many cases, the equipment and facilities, required and expected by the community.

The private hospital sector, traditionally owned and/or managed by individuals or small groups of doctors, is also undergoing significant change. There is an increasing trend towards corporate ownership, and a continued rationalisation of hospitals, partly in response to increasing cost pressures and partly in order to achieve economies of scale in the provision of services.

D. Primary Health Care

There is agreement generally that care in the community is preferable to institutionalization, wherever possible. The difficult question arises over who should and will meet the responsibility for community care.

Australians make considerable use of their primary health care system with 78.5 percent visiting a general practitioner at least once in 1986 (information supplied by the Health Benefits Operations Branch of the Department of Community Services and Health). There were approximately 18,000 medical practitioners actively involved in providing those services. Consumers also seek assistance from a significant number of other primary health care providers. The ABS found, for example, that one in twelve consultations were with a chemist in a two week survey period in 1983.

Consultations with health professionals in a two week period 1983

Type of health professional	Male	Female	Persons	Per Cent
Medical practitioner	1145.9	1525.7	2671.6	59.6
Dentist	347.4	407.2	754.7	16.8
Chemist	169.6	225.9	395.5	8.8
Chiropractor	86.6	96.3	182.9	4.1
Physiotherapist	73.7	68.0	141.7	3.2
Optician/optometrist	31.6	40.0	71.6	1.6
District, home or community nurse	24.5	38.9	63.4	1.4
Baby health nurse	8.5	9.6	8.1	0.4
School nurse	2.7	2.9	5.6	0.1
Naturopath	14.1	32.5	46.6	1.0
Acupuncturist	12.2	21.6	33.8	0.8
Chiropodist/podiatrist	8.6	21.4	29.9	0.7
Herbalist	5.8	14.1	19.8	0.4
Osteopath	9.7	8.9	18.6	0.4
Social worker/welfare officer	7.8	10.3	18.1	0.4
Psychologist	6.0	7.7	13.6	0.3
TOTALS	1954.7	2531.0	487.5	100.0

a. Some people consulated a health professional more than once in the two week period of the survey. Total persons consulting therefore exceed column totals.

Source: *Australian Bureau of Statistics (1986b) Cat No. 4311.0

III. CURRENT HEALTHCARE CLIMATE

A. Role of the Physician

It is felt that some 75% of health expenditures in Australia are effectively determined by physicians and it is they who decide when to prescribe drugs, request a follow-up, when to admit to a hospital, length of stay and when to operate.

Number of Registered Medical Practioners in Australia - Nov 1989

Type of Health practioner	Amount
Standard G.P.	15,800
Locums	106
Other G.P.'s (ie. retired, not practicing)	1,234
Salaried doctors (eg, health dept admin)	739
Resident Medical Doctors	5,229
Specialists	11,209
TOTAL	35,317

(M) 28,119, (F) 7,198

Source: Department of Health - Canberra

The fee for service system that marks the Australian medicare system means that doctors expect payment for each and every service they provide. Though publicly funded, the health care system remains largely controlled by the private medical profession, which determines when, where and how often patients are treated. Politicians and bureaucrats influence health budgets, but governments are committed to paying whatever bills doctors and hospitals submit.

B. Australian Pharmacies

The Pharmacy industry in Australia is currently involved in a massive dispute with the government over payments received for dispensing Government listed drugs, which are sold at a set price under the Pharmaceutical Benefits Scheme (PBS). The pharmacies argue that the reduction in payments by government will mean that many pharmacies will be unable to make enough money to remain viable businesses. The government maintains that there are too many chemists and that payments made for the P.B.S. in the past have been too generous.

The dependency of some businesses on these government payments indicates the failure of Australian pharmacies to aggressively market themselves as health care/promotion centres (as the USA have done) rather than mere dispensaries. Innovations in marketing seem to be greatly lacking in the industry, which is comprised of numerous small dispensary type stores or slightly larger stores which are usually members of co-operative buying groups. There are some 5,500 retail pharmacies in Australia.

Companies considering entering the HHC market in Australia should be prepared to spend time educating pharmacy employees about their products and applications, along with convincing pharmacy owners to focus part of their store space and marketing to promote Home Health Care and health promotion products, ie. self testing kits, dressings, etc.

C. <u>Home Testing Kits</u>

With the Government's attention being directed towards health promotion, it would seem quite natural to assume that home testing kits for use in the monitoring of certain health conditions, ie. blood pressure; bowel cancer; pregnancy, would be becoming increasingly popular with the public.

Apart from pregnancy testing kits, it seems that two major obstacles face the promotion of these products, and they have failed to meet with general acceptance. In North America, health insurance/medical funds will reimburse members for the purchase of many home health care items. People will then buy a product and home test knowing that they can claim it from their Health fund.

However, in Australia, private insurance claims can be submitted, but will go to a review committee, and each item will be judged on its merit, ie. whether for that item in that instance is a legitimate claim. It is easier, therefore, to go to the Doctor, because that visit is refundable, as are pathology costs for tests the Doctor carries out. There is no financial incentive to use home testing.

The second problem lies with product promotion - advertising is subject to the restrictions applied by the Health and Therapeutic goods act, therefore written or spoken promotion of these goods can only be in the form of editorials and can not be as paid advertisements. This, of course, limits the promotion of products to recommendation from Doctors, who in turn may see the use of these products as chiselling away at their business.

Needless to say, both of these factors restrict the potential of sales for home testing products.

IV. THE GOVERNMENT AND THE HOME HEALTH CONCEPT

A. The Government

The official line given by Federal Government Health Officers is that they support the Ministers statements on cutting costs in Hospitals and looking at alternatives to relieve pressure on beds and further reduce the number of beds from 5.7/1000 to 2/1000 (U.S.A. and Europe have a bed status of 4/1000 population).

The reality, however, is that funds for home health care and aftercare have been drastically cut so that major training hospitals in NSW are, in fact, now keeping patients in hospital longer, because patients cannot afford dressings and equipment.

Extensive lobbying with the government for extra funds in these areas is essential before the Home Health Care Market becomes viable.

It has been noted that financial incentives should be considered as a way of coaxing patients to be discharged as early as is medically possible.

Consideration is also being given for incentives to be paid to doctors and other health care professionals who provide preventative counselling to groups and individuals. Many general practitioners, it seems, are willing to engage in more preventative work, but the open-ended nature of the fee-for-service arrangements, as they stand, are inappropriate for reimbursing health promotion and illness prevention activities.

The Australian Medical Profession's historical insistence on fee-for-service payments is seen as a major hurdle to the growth of a Home Health Care industry.

B. Physical Aids for the Disabled Program (PADP)

Since 1981, International Year of the Disabled, the Government has funded the PADP, and it has operated in each State of Australia to enable all people with disabilities to have access to physical aids.

The scheme is run on a means tested basis, and the aids remain the property of PADP no matter how long a patient uses the aid. Supply centres are attached to public hospitals in the community, and apart from durable medical equipment, ie. wheelchairs, walking frames etc, catheters and incontinence pads are also supplied. Each centre is empowered to purchase their own products other than the disposable items, which are supplied through the hospital. Hospital purchases are made through tenders organized by the Government department of supplies.

Each state also offers the services of Independent Living Centres which provide advice to all disabled persons about equipment available to help them with day to day tasks. The centre in Sydney currently has some 1500 suppliers and 9,000 products on file.

Where people do not qualify for the PADP, the Red Cross has a scheme for the short term lease of equipment, longer term use means that patients must purchase goods through retail outlets.

C. Health Promotion Projects

Further cutbacks in non-theatre and non-essential hospital activities, resulting in the earlier discharging of patients, has been indicated by the government for the future. High cost institutional care must be replaced by structured alternatives, including greater community care programs, the care of people in their own homes and more use of hospital outreach programs.

The government is currently focussing strongly on the Health Promotion alternative targeting five priorities for health action.

These are:

1. control of high blood pressure
2. improved nutrition
3. injury prevention
4. the health of older people
5. primary prevention of preventable cancer ie. skin and lung cancer and the secondary prevention of breast and cervical cancer.

These areas will be addressed through education and group screening projects endeavouring to direct individuals to become more aware of their own responsibility for well-being.

D. Importation of Therapeutic Goods

Nearly all products for use in the Home Health Care situation are required to be registered with the Commonwealth Department of Health through the Medical Devices and Dental Products Branch.

Items are registered on the National Register of Therapeutic Devices (see Appendix A). Some products may require pre-market evaluation by the Department or must meet with pertinent Australian Standards. This system of registration and evaluation was initially based on that used by the U.S. and Canadian Health Authorities and has now been adapted to meet (Australian) Health Department requirements.

Under the Therapeutic Goods Act, to be introduced March 1st, 1990, goods will be required to be categorized into designated devices (ie: intraocular lenses, I.U.D. contraceptive devices, presthetic

heart valves, cardiac pacemakers and drug infusion systems), or non-designated devices (eg. bandages, sutures etc). Designated devices will require evaluation before being registered whereas most non-designated devices may simply be listed A scale of annual fees will be introduced to cover the cost of company registration and product registration. Products requiring evaluation will also be charged a separate fee.

The testing facility is currently located in Melbourne, Victoria:

Medical Devices & Dental Products Branch
Department of Health
250 Langridge Street
ABBOTSFORD VIC 3067

Companies who wish to list/register on the Therapeutic Good Register must have an Australian sponsor/agent.

The Department prefers to deal with the Australian agents for medical products as it provides them with a local reference point should any problem reports be received. Local agents should be familiar with the specific Australian requirements.

Test certificates from the Canadian Standards Association or Approval from the Canadian or U.S. Health Authorities do not guarantee automatic entry into the Australian market and local authorities may require further testing to be carried out.

E. Importation of Therapeutic Substances

All medicines be they presecriptive or over the counter are subject to the Guidelines prepared by the Australian Department of Health in their publication, New Drug Formulation 4 (NDF4) - Guidelines for preparing applications for the general marketing or clinical investigational use of a therapeutic substance.

Many of the over the counter preparations require a section B1 approval in which the supplier must provide chemical and quality control data for approval.

Section B2 applies to invitro and animal studies and section B3 is for studies in man.

Thus, an application in the format of the NDF4 requires the submission of chemistry, manufacturing and quality control data (in the format of Section B1), and documentation to demonstrate the product's safety and efficacy (in the format of Sections B2 and B3).

Sometimes the Department may decide that all three sections of the NDF4 are not required. For example, a known therapeutic substance may be put forward for a new use, and perhaps only B3 data would be requested.
Ethical preparations of a generic nature will require the submission of full B1 data in accordance with the NDF4 guidelines.

CONCLUSION

In summary, it appears that all indicators point towards the timeliness and logic of introducing Australians to the concept and reality of self-care/home health care. Companies looking to enter this arena will find it a challenging task.

The Federal Government's recommendation to implement a national program for better Health, centred for the next five years on Heart disease, high blood pressure, preventable cancer, health of older people and nutrition will indeed focus attention on self help, and the individual's responsibility for their own health. Whilst this is an encouranging development, the flow on will not automatically be directed to the home health care market in the early stages.

The mandate of Medicare to provide accessible medical services for all Australians, by its current nature of fees for service, does little to encourage the growth of the Home Health Care market. The Australian Retail Pharmacy is as yet not geared to handle North American style Home Health Care product marketing and a major change in philosophy, marketing direction and strategy is required. The American experience is that companies will have to devote time and training to nursing and health professionals in order to generate sales, and the same will be required in Australia.

At present there is also some difficulty in trying to gauge the true size of the Home Health Care Market, as no specific statistics are available or being collected.

Up until such time as the Australian government makes firm its policy on Home Health Care, there will be difficulties in establishing a market for homecare products. Once established, however, Australia should provide a good opportunity for aggressive, export ready firms.

TRADE PROMOTION OPPORTUNITIES

Hospmedex April 3-6, 1990

Sydney Convention Centre, Darling Harbour

Contact:
Melanie Heard
Total Concepts Exhibitions Pty Ltd
49 Hume Street
CROWS NEST NSW 2065

Tel: (02) 436 3266
Fax: (02) 439 7040

Meditex '90 July 30 - August 2

Royal Agricultural Showgrounds, Sydney
Royal Hall of Industry

Contact:
BPI Exhibition
162 Goulbourn Street
DARLINGHURST NSW 2010

Tel: (02) 266 9799
Fax: (02) 267 1223
Tlx: 121417

Pharmacy Fair July 20-23

Darling Harbour, Sydney NSW

Contact:
Mr George Skinner
c/- Pharmacy Guild of Australia
79 Lightgow Street
ST LEONARDS NSW 2065

Fax: (02) 439 6525

Aides & Appliances Expo October 1991

Biennial Event organized by the Rehabilitation unit of the Tamworth Base Hospital.

Contact:
Marion Evans
Tamworth Base Hospital & Health Service
PO Box 83
TAMWORTH NSW 2340

REFERENCES

'Health for all Australians'
Report of the Health Targets and Implementation Committee to Australian Health Ministers 1988.
Australian Government publishing service 1988.

Nursing Homes and Hostels Review
Department of Community Services and Health.
Australian Government publishing service 1986.

'First Triennial Review of the Home and Community Care Program'
Final report of the HHC review.
Working group to Commonwealth, State and Territory Ministers.
Australian Government publishing service 1989.

'Home Health Care Report' - May 1989
Richard Barnes and Associates Pty Ltd
Marketing and Research Consultants
Suite 9
Garden Mews
82-86 Pacific Highway
ST LEONARDS NSW 2065

'Who Pays? Financing Services for Older People'
Edited: Chris Fosler Hal L Kendig
Commenwealth Policy Co-ordination Unit & Australian National University, Ageing and Family Project, Canberra 1987

CONTACTS

Independent Living Centre
600 Victoria Road
RYDE NSW 2112
Tel: (02) 808 2233
Contact: Ruth Grayson - Director

Physical Aids for the Disabled Programme
NSW Department of Health
Level 23
McKell Building
Rawson Place
SYDNEY NSW 2000
Tel: (02) 217 5878
Contact: Valerie Lord - State Co-ordinator

Pharmacy Guild of Australia
79 Lithgow Street
ST LEONARDS NSW 2065
Tel: (02) 438 3333
Fax: (02) 439 5625

National Register of Therapeutic Goods
Dept of Community Services & Health
GPO Box 9848
CANBERRA ACT 2601
Tel: (062) 860 249
Tlx: 61209
Fax: (062) 816 946
Contact: Natalie Trafford, Information Officer

MAJOR MANUFACTURERS ACTIVE IN THE AUSTRALIAN MEDICAL EQUIPMENT AND HEALTH CARE MARKET

Company	Products & Services
Abbott Australian Holdings Pty Ltd Captain Cook Drive KURNELL NSW 2230 Tel: (02) 668 9711 Tlx: AA 120812 Parent: Abbott Laboratories North Chicago, USA	Pharmaceutical drugs and medicines, hospital products, diagnostic instruments, nutritionals, hair and eye care products
Ansell Medical South Gippsland Highway DANDENONG VIC 3175 (03) 791 2055 Fax: (03) 791 4579 Tlx: AA 34132	Ambidextrous examination gloves (sterile and non-sterile), forceps, dissecting surgical Tel: gloves, wound closure system
Australian Pharmaceutical Industries PO Box 123 WENTWORTHVILLE NSW 2145 Tel: (02) 683 0683 Fax: (02) 683 6193	
Baxter Healthcare Pty Ltd Oakes Road OLD TOONGABBIE NSW 2146 Tel: (02) 688 9111 Fax: (02) 688 9123 Tlx: AA 23126	
Boehringer Mannheim Australia Byfield Street RYDE NSW 2113 (02) 888 2122 Fax: (02) 888 5619 Tlx: AA 22955	Biochemistry analysers, blood 6-8 glucose meters, blood glucose NORTH test strips, cell counters, Tel: chemicals and reagents, diagnostic reagents and apparatus, urine test strips

Company	Products & Services (cont'd)
De Puy (division of Boehringer Australia)	Anti-embolish stockings, Mannheim crutches, medical tapes, occupational therapy equipment, orthopaedic implants, orthopaedic softgoods, physiotherapy equipment, splinting and cashing supplies, surgical braces and surgical corsets
Edwards Medical Box 27 NARELLAN NSW 2567 Fax: (046) 55 2644	Incontinence pads, lab equipment PO for Biotech field
Grajen Medical Aids 247 Henley Beach Road TORRENSVILLE SA 5031 Tel: (08) 43 5399	Shower fittings for disabled
Johnson & Johnson Australia Pty Ltd 154 Pacific Highway LEONARDS NSW 2065 Tel: (02) 439 0066 (02) 439 4128 Tlx: AA 24610	Brand names; critikon (cardiac catheters), extracorporeal (haemodialysis accessories), j-ST vac (closed wound drainage systems), holter IV (pumps and Fax: sets), simplicity IV (pumps and sets), oxychek (oxygen monitors), berman (ongiographic catheters),jelco IV (catheters)
Kimberly-Clark Australia Pty Ltd 20 Alfred Street MILSONS POINT NSW 2061 Tel: (02) 929 7133 Fax: (02) 957 5687 Tlx: AA 21266	Paper manufacturers, converters and distributors
Nucleus Limited 5 Sirius Road LANE COVE NSW 2066 Tel: (02) 428 1011	Distributor of medical equipment manufactured by Japanese company, Nihon Kohden

Company	Products & Services (Cont'd)
Smith & Nephew (Aust) Pty Ltd 211-225 Wellington Road CLAYTON VIC 3168 (PO Box 150) (03) 566 1200 Fax: (03) 560 9479 Tlx: AA 31926	Blood lancets, disposable scalpels, hypodermic needles, paediatric urine collection bags, scalpel blade removers, Tel: stitch cutters, surgical blades, syringe/needle destructors, urinary/drainage bag
The Boots Company (Aust) Pty Ltd 21 Loyalty Road NORTH ROCKS NSW 2151 Tel: (02) 630 5555 Tlx: AA 27410 Parent; The Boots Company Plc, UK	Manufacturer and distributor of pharmaceuticals, sterile injectables, sweeteners, cosmetics, toiletries, surgical plastics and bandages
3M Australia Pty Ltd 950 Pacific Highway PYMBLE NSW 2073 Tel: (02) 498 9333	Brand names (related to medical field); Blenderm (surgical tape), Coban Celastic (bandages), Filtron (surgical mask), Iso- drape (surgical drape), Littman Parent; Minnesota Mining & (stethoscopes, EGC mounting Manufacturing Co, USAsystems, nurescope), Micropore (surgical tape), Steri-Drape (surgical drapes), transpore (surgical tape), Trimax (x-ray film, intensifying screen), 3M (film cleaners, surgery instruments, porcelain, rubber, cable term systems)

APPENDIX A

GUIDELINES FOR IMPORTERS OF THERAPEUTIC SUBSTANCES INTO AUSTRALIA

The Department of Community Services and Health controls the importation and distribution of therapeutic substances into Australia. This control is administered under the legislative provisions of the Customs (Prohibited Imports) Regulations and the Therapeutic Goods Act.

> "Therapeutic Substance" means a substance, including a mixture or compound of substances, that has a therapeutic use and includes a surgical ligature, suture or dressing.
>
> "Therapeutic Use" means a use for the purpose of:
>
> A. Preventing, diagnosing, curing or alleviating of a disease, ailment, defect or injury in persons or in animals;
>
> B. The influencing, inhibiting or modifying of a physiological process in persons or animals; or
>
> C. The testing of the susceptibility of persons or animals to a disease or ailment.

For the purpose of the Therapeutic Goods Act, "goods for therapeutic use" means goods that are, whether in writing or otherwise, represented to be, or are likely to be taken to be, for therapeutic use, and includes goods for use in contraception and testing for pregnancy.

Persons or companies wishing to import therapeutic substances into Australia must make an application in writing to this Department. Applicants should allow a minimum of 28 days for their application to be considered and NO "into-store" permits will be issued within this 28 day period. Before a permit or permission to import is granted the Secretary to the Department may require such information as is necessary to establish that the substance proposed for importation conforms to acceptable standards of quality, safety and efficacy.

FINISHED PRODUCTS OF THE 'OVER THE COUNTER' TYPE

Products consisting of therapeutic substances and excipients already used in products available on the Australian market will be considered for importation. Applications should be accompanied by:

A. Completed Form H1312 - National Register of Therapeutic Goods which must give full formulation details and listing all substances in the formulation using Australian Approved Names or chemical names if substances do not have Australian Approved Names. (Herbal ingredients by correct botanical name.) The actual amounts of each active ingredient per dosage unit in descending numerical order must also be stated. If colourings are included indicate the Colour Index Number.

B. Draft copies or mock-ups of all labelling, packaging and promotional material which it is proposed to use for distribution in Australia. Draft labels and packaging submitted must confirm to Therapeutic Goods Order No 22 described in the next section.

C. Certificate of Pharmaceutical Product for each item, issued by the Regulatory Authority in the Country of Origin.

The Commonwealth Department of Community Services and Health expects that responsibilities relating to State Health Regulations will be complied with by the importer. State Health Departments should be consulted if necessary.

Following examination of this information by the Department applicants will be advised of any further details which may be required.

LABELS

Applicants are provided with a copy of THERAPEUTIC GOODS ORDER NO 22 with which all labels and packaging for therapeutic goods marketed in Australia are expected to conform in all respects.

The Department requires that labels for all finished products imported into Australia shall include the following information in English:

1. The name of the product.

2. The names of all active ingredients in the product.

a. where there is an Australian Approved Name the ingredient must be indentified by that name;

b. where there is no Australian Approved Name the name provided on the label shall be a name approved by the Secretary to the Department of Community Services and Health; and

c. where an active ingredient is of herbal origin the internationally recognised botanical name (Latin) shall be stated.

3. The quantity or proportion of all active substances in the product.

4. The name of the dosage form.

5. The quantity of the goods in the package.

6. Warning statements, if any.

7. The Batch Number of the goods immediately preceded by the words Batch No. or the symbol (B).

8. Expiry date in approved format.

9. Storage conditions.

10. Directions for use.

11. The name and address of the Australian distributor. This must include street name and street number. Post Box numbers or codes are not acceptable.

ALSO

12. Under the terms of the Commerce (Imports) Regulations labelling must include the name of the country in which the goods were made or produced, in prominent and legible characters.

Applicants should read the above details in conjunction with Therapeutic Goods Order No 22 as there may be other requirements on certain types of goods.

WEIGHTS AND MEASURES

The metric system is the official system of weights and measures in Australia. Substances should be labelled in descending order of weight or volume.

THERAPEUTIC CLAIMS

For 'over the counter' medications, claims must conform to the Media Council of Australia Therapeutic Goods Advertising Code and the NSW Therapeutic Goods and Cosmetics Act (if the goods are to be sold in NSW). Generally modest claims which do not contravene the Advertising Code, are permitted. Extravagant, unsubstantiated and illegal claims are not permitted and applications containing such claims will be returned.

There may be additional restrictions on permitted claims for certain classes of products, eg. Slimming Products, Hair and Scalp products, Vitamins etc.

If more than one language is to be used - claims which are not permitted in English, may not be made in other languages.

CERTIFICATION FOR FINISHED PRODUCTS

Australian manufacturers of therapeutic goods are inspected regularly by authorised personnel from both State and Federal Health authorities to ensure that their manufacturing facilties and procedures are of satisfactory standards as recommended in the voluntary Australian Code of Good Manufacturing Practice.

In order to ensure that imported therapeutic substances of this type are of comparable standard, intending importers are requested to provide, in addition to the above information, "Certification of Pharmaceutical Product".

Such certifications are issued by the Health authorities of nations signatory to the World Health Organisation agreement and in accordance with guidelines issued by the World Health Organisation in relation to the manufacturing quality of Pharmaceutical Products moving in International Commerce.

In some instances Certification of Pharmaceutical Product cannot be obtained from the country of origin because:

1. That country is not signatory to the World Health agreement; or

2. The product is not classed as a therapeutic substance (for example, some countries consider vitamin compounds to be nutritional substances).

In these circumstances, the Department expects that an appropriate Regulatory Body (eg. State or Province), of the country in which the product was manufactured will issue Certification to demonstrate that:

   a. the goods are manufactured in accordance with a recognised Code of Goods Manufacturing Practice.

b. the premises and manufacturing procedures are regularly inspected to ensure compliance with the Code.

c. the goods are on free sale within the country of origin, and do not contravene that Country's Regulations for such goods. For goods originating from the USA, this statement must come from the FDA.

AUSTRALIA

Area	7,682,300km²
STATES	**POPULATION**
New South Wales	5,544,000
of which Sydney	3,392,000
Victoria	4,165,000
of which Melbourne	2,917,000
Queensland	2,593,000
of which Brisbane	1,157,000
South Australia	1,373,000
of which Adelaide	987,000
Western Australia	1,441,000
of which Perth	1,001,000
Tasmania	446,000
of which Hobart	178,000
Northern Territory	148,000
of which Darwin	68,000
Australian Capital Territory	265,000
of which Canberra	265,000
Total Population:	approx 16,000,000

	Exports (billion CAD)	Imports
Food & live animals	8.1	1.4
Crude materials	9.0	1.1
Chemicals	0.5	3.0
Mineral fuels	8.0	2.0
Manufactured goods	3.3	5.7
Machinery	1.7	15.2
Total	33.0	35.0
Imports/Exports	**To**	**From**
Asean	7%	5%
China	5%	5%
EEC	14%	24%
Japan	28%	24%
USA	10%	21%
Canada	1.5%	2%

Canadian Exports to Australia	
Visible	850 million CAD
Services	175 million CAD
Australian Exports to Canada	
Visible	550 million CAD
Services	60 million CAD
Australian Investment in Canada	1.5 billion CAD (1988)
Canadian Investment in Australia	3.3 billion

Climate	Tropical (39%) and Temperate (61%)
Languages	English
Weights & Measure	Metric
Electrical Power	220V 3 Phase 50Hz
Average Earnings (1987)	CAD400 per week
Principal Crops	Wheat, Barley, Oats, Grain, Sorghum, Sugar cane
Motor Vehicles	9 million
GDP (1988)	CAD240 billion